WYETH-AYERST RESEARCH

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Division of American Home Products Corporation

U.S. REGULATORY AFFAIRS

June 8, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99D-0254: Draft Guidance for Industry: Product Name Placement Size, and Prominence in Advertising and Promotional Labeling

Dear Sir or Madam:
Wyeth-Ayerst Laboratories, a division of American Home Products Corporation, appreciates the opportunity to respond to the Food and Drug Administration's request for comments regarding the draft guidance titled "Guidance for Industry: Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling" Docket No. 99D-0254 as announced in Federal Register notice 64 FR 12341 (March 12, 1999).

Wyeth-Ayerst is a major research-oriented pharmaceutical company with leading products in the areas of women's health care, cardiovascular and metabolic disease therapies, central nervous system drugs, anti-inflammatory agents, vaccines and generic pharmaceuticals. American Home Products Corporation is one of the world's largest research-based pharmaceutical and health care products companies, and is a leading developer, manufacturer and marketer of prescription drugs and over-the-counter medications.

The purpose of this communication is to provide the Agency with Wyeth-Ayerst's comments to this draft guidance for industry. Our comments are based on the italicized draft guidance text as shown below.

> *"The guidance states that "FDA interprets this provision (21 CFR 201.10(g)(1) and 202.1(b)(1)) as precluding separation of the proprietary or trade name and the established name or proper name by placement of a logo, trademark, or other graphic matter, or otherwise physically separating the proprietary and established name. The established or proper name should be placed either directly to the right of or directly under the proprietary name. There should be no intervening matter that in any way would detract, obfuscate, or de-emphasize the established or proper name."*

Wyeth-Ayerst Comments
Placement of a logo, trademark or other graphic matter
With respect to the placement of a logo, trademark or other graphic matter separating the proprietary name and the established name, we assume that the Agency is not defining "logo, trademark or other graphic matter" to include the actual trademark for a proprietary name. Please be advised that, by convention, the actual trademark symbol for a proprietary name, i.e. R in circle for a registered trademark (®) or TM for an unregistered trademark (™), immediately follows the proprietary name. Accordingly, the regulations should not conflict with, or purport to require a change in this long term practice of trademark law.

Graphic displays of the proprietary and established name
There are various ways to display and give prominence to the brand and generic names of drugs when used in graphic displays. For example, we believe that it is acceptable for the brand or proprietary name to appear immediately above the established or generic name. Further, we believe that the placement of a line between

99D-0254

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these names does not de-emphasize the established or generic name associated with the proprietary name.

Additionally, in graphic displays, Wyeth-Ayerst does not believe that it is always necessary for the established name to either be to the right or directly under the brand or proprietary name in graphical displays. In fact in the recent past, FDA has pre-cleared launch materials with the generic name above and to the left of the proprietary name. This should not be prohibited now. It is possible to provide visual prominence to the established name if it is on top or to the left of the proprietary name as long as both names are in close proximity to each other and the identification of which name is brand and which is established is clear and understood. We therefore recommend the deletion of the sentence "The established name should be placed either directly to the right of or directly under the proprietary name." We further recommend that the draft guidance state "Intervening matter should not detract, de-emphasize or obfuscate the established or proper name" in lieu of "There should be no intervening matter that in any way would detract, obfuscate, or de-emphasize the established or proper name."

We look forward to the Agency's review of our comments. Please contact me at (610) 902-3772 if there are any questions about this submission.

Sincerely,
WYETH-AYERST LABORATORIES

Jennifer W. Phillips, Pharm.D., Director
Women's Healthcare
U.S. Regulatory Affairs

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